

Second Preliminary Amendment
Serial number 10/705,255

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

17. (Currently Amended) A method of preventing or treating radiation-induced cystitis of the bladder area comprising instilling into the bladder of a human or an animal, a composition comprising hyaluronic acid having an average molecular weight of not less than about 2×10^5 Daltons, a pharmaceutically acceptable carrier, and an agent, wherein the agent is an antiseptic, antibacterial, antifungal, immunotherapeutic, immunosuppressive, chemotherapeutic, or pH modifying agent, wherein the instillation of the composition occurs before or after ~~is followed~~ by administering radiotherapy treatment to the bladder area.

18. (Previously presented) The method of claim 17, wherein the agent is an antibacterial.

19. (Previously presented) The method of claim 17 wherein the antibacterial is aminoglycoside, cephalosporin, gentamycin, macrolide, nitrofurantoin, penicillin, quinolone, suphonamide, tetracycline, trimethoprim, bacitracin, neomycin, chlorhexidine, or mandelamine.

20. (Previously presented) The method of claim 17, wherein the agent is an antifungal.

21. (Previously presented) The method of claim 17, wherein the antifungal is amphotericin B or fluconazole.

22. (Previously presented) The method of claim 17, wherein the agent is an immunotherapeutic.

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23. (Previously presented) The method of claim 17, wherein the immunotherapeutic is bacterial cell extracts, mycobacterial cell wall extracts, live and inactivated bacillus Calmette-Guerin, bacillus Calmette-Guerin extracts, cytokines, interferons, interleukins, prostaglandins, or immune stimulants of viral, chemical and molecular biological origin effective for treating disorders of the bladder.

24. (Previously presented) The method of claim 17, wherein the agent is an immunosuppressive.

25. (Previously presented) The method of claim 17, wherein the immunosuppressive is a prostaglandin or corticosteroid.

26. (Previously presented) The method of claim 17, wherein the agent is a chemotherapeutic.

27. (Previously presented) The method of claim 17, wherein the chemotherapeutic is cisplatin, cyclophosphamide, doxorubicin, vincristin, mitomycin-C or thiotepa.

28. (Previously presented) The method of claim 17, wherein the agent is a pH modifying agent.

29. (Previously presented) The method of claim 17, wherein the pH modifying agent is sodium acid phosphate or sodium bicarbonate.

30. (Previously presented) The method of claim 17, wherein the agent is a glycosaminoglycan.

31. (Previously presented) The method of claim 17, wherein the glycosaminoglycan is heparin, heparan sulfate, pentosanpolysulfate, dermatan sulfate, chondroitin sulfate and keratanosulfate.

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32. (New) A method of treating radiation-induced cystitis of the bladder area comprising instilling into the bladder of a human or an animal, a composition comprising hyaluronic acid having an average molecular weight of not less than about 2×10^5 Daltons, and a pharmaceutically acceptable carrier, after administering radiotherapy treatment to the bladder area.

33. (New) The method of claim 32, wherein the average molecular weight of the hyaluronic acid is between about 2×10^5 Daltons and about 3.1×10^6 Daltons.

34. (New) The method of claim 32, wherein the hyaluronic acid is an amount between about 5 mg and about 1000 mg.

35. (New) The method of claim 32, wherein the composition is administered in a volume of between about 1 ml and about 500 ml.

36. (New) The method of claim 32, wherein the administration of the composition occurs about 1 minute to about 4 hours after the radiotherapy treatment.

37. (New) The method of claim 32, wherein the administration of the composition is such that the composition remains in the bladder for about 1 minute to about 4 hours after the radiotherapy treatment.

38. (New) The method of claim 32, wherein the radiotherapy of the bladder area is for treatment of a cancer, wherein the cancer is bladder cancer, prostate cancer, rectal cancer, uterine cancer or cervical cancer.

39. (New) The method of claim 32, wherein the radiotherapy of the bladder area is for treatment of prostate cancer.

40. (New) The method of claim 32, wherein the hyaluronic acid is an amount

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between about 10 mg and about 500 mg.

41. (New) The method of claim 32, wherein the hyaluronic acid is an amount between about 25 mg and about 100 mg.

42. (New) The method of claim 32, wherein the composition is administered in a volume of between about 10 ml and about 250 ml.

43. (New) The method of claim 32, wherein the composition is administered in a volume of between about 20 ml and about 100 ml.

44. (New) The method of claim 32, wherein the administration of the composition occurs about 2 minutes to about 2 hours after the radiotherapy treatment.

45. (New) The method of claim 32, wherein the administration of the composition occurs about 5 minutes to about 1 hour after the radiotherapy treatment.

46. (New) A method of reducing radiation-induced cystitis of the bladder area, comprising instilling into the bladder of a human or an animal a composition comprising hyaluronic acid having an average molecular weight of not less than about 2×10^5 Daltons, and a pharmaceutically acceptable carrier after administering radiotherapy treatment to the bladder area.

47. (New) The method of claim 46, wherein the average molecular weight range of the hyaluronic acid is between about 2×10^5 Daltons and about 3.1×10^6 Daltons.

48. (New) The method of claim 46, wherein the hyaluronic acid is an amount between about 5 mg and about 1000 mg.

49. (New) The method of claim 46, wherein the composition is administered in a volume of between about 1 ml and about 500 ml.

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50. (New) The method of claim 46, wherein the administration of the composition after the radiotherapy treatment occurs about 1 minute to about 4 hours after the radiotherapy treatment.

51. (New) The method of claim 46, wherein the administration of the composition is such that the composition remains in the bladder from about 1 minute to about 4 hours after the radiotherapy treatment.

52. (New) The method of claim 46, wherein the radiotherapy of the bladder area is for treatment of a cancer, wherein the cancer is bladder cancer, prostate cancer, rectal cancer, uterine cancer or cervical cancer.

53. (New) The method of claim 46, wherein the radiotherapy of the bladder area is for treatment of prostate cancer.

54. (New) The method of claim 46, wherein the hyaluronic acid is an amount between about 10 mg and about 500 mg.

55. (New) The method of claim 46, wherein the hyaluronic acid is an amount between about 25 mg and about 100 mg.

56. (New) The method of claim 46, wherein the composition is administered in a volume of between about 10 ml and about 250 ml.

57. (New) The method of claim 46, wherein the composition is administered in a volume of between about 20 ml and about 100 ml.

58. (New) The method of claim 46, wherein the administration of the composition occurs about 2 minutes to about 2 hours after the radiotherapy treatment.

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59. (New) The method of claim 46, wherein the administration of the composition occurs about 5 minutes to about 1 hour after the radiotherapy treatment.